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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/593,591   | 06/13/2000  | Gary K. Michelson    | 101.0078-00000      | 5619             |
| 22882  | 7590        | 05/27/2010           | EXAMINER            |                  |
| MARTIN & FERRARO, LLP<br>1557 LAKE O'PINES STREET, NE<br>HARTVILLE, OH 44632 |             |                      |                     | PREBILIC, PAUL B |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 3774   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/593,591             | MICHELSON, GARY K.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Paul B. Prebilic       | 3774                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 March 2010.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) See Continuation Sheet is/are pending in the application.

4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) See Continuation Sheet is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/16/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____.                         |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7-20,22-30,32-44,46,47,49-86,88,89,91-129,148-164,166,168-184,186,188-204,206,208-224,226,228-264,266,268-286,288,289,291,292,294,295,297,298 and 300.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 43,44,46,47,49-84,153-157,183,184,186,188-202 and 243-262.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,158-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 268-286, 288, 289, 291, 292, 294, 295, 297, 298, and 300.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 16, 2010 has been entered.

### ***Election/Restrictions***

Claims 43, 44, 46, 47, 49-84, 153, 154-157, 183, 184, 186, 188-202, and 243-244, 246, 248-262 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 26, 2005.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,158-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 268-286, 288, 289, 291, 292, 294, 295, 297, 298, and 300 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Upon further review of the present claim language, the Examiner determined that the present claims appear to contain new matter with respect to the original disclosure. In particular, the language in the independent claims such as:

- "said opening having a maximum length in a direction parallel to the mid-longitudinal axis" (e.g. claim 1, lines 27-28) with "maximum width being greater than the maximum length" (e.g. claim 1, lines 38-39) lacks support because there is no special definition for "mid-longitudinal axis" so it runs along the longest dimension.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,4,5,7-20,22-30,32-42,85,86,88,89,91-129,148-152,158-164,166,168-182,203,204,206,208-224,226,228-242,263,264,266 268-286, 288, 289, 291, 292, 294, 295, 297, 298, and 300 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new terminology "substantially the same configuration as the perimeter of the natural medullary canal present when the major long bone is cut transverse to the medullary canal to form the bone ring" (see e.g., claim 1, lines 25-27) is indefinite because it is not clear from the specification how and to what degree "substantially"

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modifies "the perimeter of the natural medullary canal" as claimed. In other words, "substantially" is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know how much the natural shape can be modified and still fall within the claim scope. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

*"We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples." (emphasis added here)*

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially naturally shaped perimeter and what does not. This feature is a critical and defining limitation of the claim. It must be clear as to what falls within the scope of the claim(s).

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required: as an alternative to the Section 112, first paragraph new matter rejection set forth above, the Examiner assert that even if the claimed features

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were shown to have inherent support, they would at least lack any antecedent basis from the specification.

***Claim Rejections Based Upon Prior Art***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 5, 7-20, 22, 25, 30, 32-35, 85, 86, 88, 89, 91-106, 109, 114-119, 127-129, 148, 158, 163, 164, 166, 171, 174, 175, 179, 180, 203, 204, 206, 208-211, 213-215, 219, 220, 223, 224, 226, 228-231, 233-235, 239, 240, 263, 264, 266, 268-271, 273-275, 279, 280, 285, 288, 291, 294, 297, and 300 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone. Boyle discloses a bone ring obtained from a long bone (Figures 5, 10, 12, and column 2, lines 28-55) that has all the claimed structure except for non-arcuate upper and lower surfaces and the opening that is non-circular having a dimension that is greater along an axis than along another axis as claimed. However, since Boyle teaches in other embodiments that it was known to utilize non-arcuate upper and lower surfaces (see Figures 1, 3, 9, 12, and 13), it is the Examiner's position that it would have been obvious to make the Figure 19 embodiment with non-arcuate upper and lower surfaces for the same reasons that Boyle utilizes the same in the other embodiments.

Additionally, Boyle does disclose that the implant is obtained from the diaphysis of a long bone where the intramedullary canal defines the opening as claimed; see column 2, lines 40-55. For this reason, it is the Examiner's position that it would have been at least obvious to make the Boyle implant with the opening along one axis longer than another because the medullary canal shape is that of a natural canal that is as non-circular as the Applicant's opening. Moreover, the mere change in shape or aesthetic design has been held to be obvious absent some showing or evidence that such a change has a significant mechanical function; see MPEP sections 2144.04 I, IV that are incorporated herein by reference. It is further noted that there is no reason given for the location of the opening in the specification so it is considered obvious absent some persuasive evidence that such a particular configuration was significant; see *In re Daily*, 357 F.2d 669, 149 USPQ 47 (CCPA) 1966), and MPEP 2144.04 IV B.

Regarding claims 25 and 109, the plural openings are the pores in the bone that are naturally present in such material.

Claims 26-29, 110-113, 149-152, 159-162, 172, 177, 178, 182, 212, 217, 218, 222, 232, 237, 238, 242, 272, 277, 278, and 282 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone further in view of Kozak et al (US 5,397,364). Boyle fails to disclose the screw holes and screws as claimed. However, Kozak teaches that it was known to put multiple bone screws in similar implants as a means to secure them; see Figures 24 and 25 and the textual description of these figures. Therefore, it is the Examiner's position that it would have been obvious

to use bone screws and have holes for them in the Boyle implant for the same reasons that Kozak uses the same: to secure the implant to the adjacent bone.

With regard to claims 28 and 29, it is the Examiner's position that it would have been *prima fascia* obvious to make the bone screws and other bone implant components out of bone because the ring itself is made of that material. Since the ring itself is made of bone material, it would have been obvious to make the other parts of the implant out the same material because it would have all the advantages and purposes that led Boyle to make the bone ring out of bone or composites of bone.

Claims 36-42, 120-126, 166, 168-170, 173, 181, 206, 221, 241, and 281 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al alone. Boyle et al fails to disclose the types of growth promoting substances claimed. However, the Examiner posits that the type of growth promoting substance would have been *prima fascia* obvious over Boyle et al because there is no criticality for such types shown or demonstrated. For example, in column 4, lines 10-13, Boyle discloses putting bone growth material into the opening (26). The specific type of bone implant material claimed would amount to a substitution of a functionally equivalent bone growth material for another one as disclosed by Boyle. For this reason, it would have been *prima fascia* obvious to an ordinary artisan to substitute one bone growth material for another since the other one would function equally well.

Claims 23, 24, 107, 108, 176, 216, 236, and 276 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al alone further in view of Zdeblick et al (US 5,669,909). Boyle et al renders obvious the claim language as explained in the

rejection of claim 1 above but fails to disclose more than one bore through the upper and lower surfaces as claimed. Zdeblick et al, however, teaches that it was known to have more than one hole in similar implants; see the figures. Hence, it is the Examiner's position that it would have been obvious to have two or more holes in the Boyle et al implant for the same reasons that Zdeblick et al has the same and in order to promote greater ingrowth.

Claims 283, 286, 289, 292, 295, and 298 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al (US 6,277,149) alone further in view of Tienboon (US 5,861,041). Boyle meets the rejection as explained in the rejection of claim 1 by Boyle *supra*, but fails to teach a generally oval shape or a greater width than length as claimed. However, Tienboon teaches that generally oval openings with width greater than lengths as claimed were known; see, e.g., Figure 11. Therefore, it is the Examiner's position that it would have been obvious to make the opening generally oval with a greater width than length as claimed for the same reasons that Tienboon does the same.

### ***Response to Arguments***

Applicant's arguments filed March 16, 2010 have been considered but were considered unpersuasive.

In traversing the Section 112, first paragraph rejection, the Applicant argues that the language pertaining to the mid-longitudinal axis has original support. In response, the Examiner notes that a mid-longitudinal axis, by definition, runs along the length of the object it pertains. Therefore, a mid-longitudinal axis of Figure 10 would run vertically

on the page that Figure 10 is located. For this reason, the Examiner cannot see how the Applicant can say that opening (114) has a maximum width transverse to a mid-longitudinal axis when it appears that the opening is actually wider along a mid-longitudinal axis not transverse to it. Furthermore, the Figures are not drawn to scale so one cannot utilize them to determine relative dimensions; see MPEP 2125 under the heading "PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE" that is incorporated herein by reference. For this reason, the rejection has been maintained.

Additionally, the Applicant argues that there is a special definition for "mid-longitudinal axis" on page 3, lines 14-16 of the specification. Upon review of the entire disclosure of this issue (page 3, lines 11-17), the Examiner concluded that there is not special definition contained therein because the definition given is merely "By way of example not limitation." For this reason, the Applicant is not held to a special definition and has not redefined this term. Definition that are merely exemplary or state that they are not limiting the term cannot be taken to be special by any reasonable Examiner.

With regard to the rejections utilizing Boyle as a base reference, the Applicant argues that the claims require an opening that is wider transverse to the mid-longitudinal axis. However, as pointed out earlier, the mid-longitudinal axis runs along the longitudinal axis by ordinary definition. Therefore, the argument that the claim language is not met because of the opening orientation and shape is not based upon the claims as they are written and reasonably interpreted.

Furthermore, it is the Examiner's position that it would have been at least obvious to make the Boyle implant with the opening along one axis longer than another because the medullary canal shape is that of a natural canal that is as non-circular as the Applicant's opening. Moreover, the mere change in shape or aesthetic design has been held to be obvious absent some showing or evidence that such a change has a significant mechanical function; see MPEP sections 2144.04 I, IV that are incorporated herein by reference. It is further noted that there is no reason given for the location of the opening in the specification so it is considered obvious absent some persuasive evidence that such a particular configuration was significant; see *In re Daily*, 357 F.2d 669, 149 USPQ 47 (CCPA) 1966), and MPEP 2144.04 IV B.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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/Paul Prebilic/  
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Art Unit 3774